INSTRUMENT FOR INSERTION OF AN ENDOTRACHEAL TUBE

FIELD OF THE INVENTION

The present invention relates to an instrument or stylet for insertion of an endotracheal tube. More particularly, the present invention provides an optical stylet for insertion of an endotracheal tube, with the optical stylet having an imaging system to allow a user to accurately guide the instrument during insertion of the endotracheal tube.

BACKGROUND OF THE INVENTION

Endotracheal tubes are typically inserted into patients to provide a patent and protected breathing passage when a patient is unconscious, paralyzed, critically ill and requiring mechanical ventilation or has sustained an injury or trauma which could result in swelling or other obstruction of the airway. Laryngoscopes and bronchoscopes having fiber-optic imaging to facilitate rapid visualization of the larynx are known in the art.

One common prior art method utilizes a laryngoscope held in one hand of the operator. The blade of the laryngoscope displaces the tongue and other tissue allowing the operator to directly visualize the entrance to the larynx. The endotracheal tube, held by the other hand of the operator, is then placed into the trachea. Often a malleable metallic stylet is utilized to allow easier insertion of the endotracheal tube by forming the stylet (and hence the tube carried on the stylet) to the proper shape or contour for insertion. Because of numerous intervening factors, visualization may be impossible and repeated attempts at laryngoscopy may be dangerous. Optimal patient positioning is not always possible in many settings, and this renders laryngoscopy less effective. Furthermore, there are many patient related conditions which may limit the effectiveness of this technique, including the inability to tilt the patient's head to the proper orientation, the inability to open the patient's mouth sufficiently wide, the presence of buck teeth, a floppy epiglottis, anterior glottic orientation, and broken bones in the face or jaw, among others. Any of these can contribute to the inability to secure a patient's airway. This can and does result in death or significant morbidity in the operating suite, emergency room and elsewhere.

Another known intubating system utilizes a laryngoscope having fiber optic imaging and a light source which are fitted on the end of a rigid blade. With practice, the user can visualize the trachea and larynx area through an eyepiece provided on the laryngoscope. A thin metal stylet is attached to the laryngoscope to allow the endotracheal tube to be inserted into the larynx. This system has not met with wide approval for several reasons. The overall system is bulky and not easy for the operator to place into and manipulate within the patient's mouth. The point of visualization is at the end of the rigid blade, not at the end of the endotracheal tube. Thus, the endotracheal tube or other structures may often obscure the necessary view. Additionally, the stylet is not adjustable once in place, making it technically difficult to guide the endotracheal tube into the larynx, even with optimum visualization.

Another known methodology provides a flexible bronchoscope that allows the endotracheal tube to be directed into the trachea under direct visualization. Only the tip of the bronchoscope can be reliably controlled by the operator as it is advanced. This genre of device was initially developed from a diagnostic tool and has not proved useful in many

emergency settings. Conceptually, it is problematic to push a loose, cable-like instrument over and around tissue structures which statically or dynamically deflect it. Thus the bronchoscope often curls and may even double back on itself making visualization futile and advancement impossible.

Recently, a stylet has been provided with a lighted distal end. Light is provided by a bulb located at the distal end of the stylet and wires provide current to the bulb. Power is provided by batteries located in the body located at the proximal end of the stylet. The endotracheal tube is installed over the stylet, and the endotracheal tube/stylet are inserted through the patient's mouth toward the glottis. In a dimly lit or dark room, the operator observes the lighted distal end of the stylet shining through the skin of the patient's neck and thorax as the stylet/endotracheal tube are inserted into the proper position in the trachea. This is done without direct visualization of patient anatomy.

The present invention is a result of observation of the limitations with the known prior art devices. These limitations are well documented in the emergency room and anesthesia literature and have very real clinical implications. See Jonathan L. Benumof, M.D., *Management of the Difficult Airway,* 75 Anesthesiology 1087–1110, 1991; Jonathan L. Benumof, M.D., *Management of the Difficult Airway: The ASA Algorithm,* 45th Annual Refresher Course Lectures and Clinical Update Program, American Society of Anesthesiologists, Oct. 15–19, 1994.

The present invention provides a new and significant improvement in the approach to managing the difficult airway.

SUMMARY OF THE INVENTION

Briefly stated, the present invention provides an instrument for insertion of an endotracheal tube into a patient. The instrument comprises a formable shaft having first and second ends, and a plurality of longitudinally extending passageways defined therethrough. The instrument further includes a housing having first and second ends, with the second end of the housing being connected to the first end of the formable shaft. An image guide cable having a first end and a second end is also provided. The image guide cable is disposed in a first longitudinally extending passageway of the shaft. An eyepiece is affixed to the first end of the housing and optics associated with the eyepiece are provided in the housing. The optics are optically connected with the first end of the image guide cable. A light source is attached to the second end of the formable shaft proximate the second end of the image guide cable. A baffle member is attached to the second end of the formable shaft proximate to a second longitudinally extending passageway. The baffle member has an opening directed toward the first longitudinally extending passageway. A fluid port is located on the housing. The fluid port is in fluid communication with the second passageway. A first opening is provided in communication with a third longitudinally extending passageway in the formable shaft. The first opening is located on the second end of the formable shaft on an opposite side of the first passageway from the baffle member. A suction port is also provided located on the housing. The suction port is in fluid communication with the third passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of the preferred embodiment of the invention, will be better understood when read in conjunction with the